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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,563	03/29/2004	Victor L. Serebruany	0004.0001-000	1385

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EXAMINER	
PAGONAKIS, ANNA	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
06/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/811,563	SEREBRUANY, VICTOR L.	
	Examiner	Art Unit	
	ANNA PAGONAKIS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/3/2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-14,22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-14,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's payment and submission filed 6/3/2009, has been received and entered into the present application. Accordingly, prosecution has been reopened.

Applicant's reply filed have been received and entered into the present application. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 5-14 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitney et al (U.S. 6,180,660 B1) in view of Khan et al (Journal of Clinical Investigation, Vol. 103, No. 6, 1999, provided by Applicant) and Gershlick et al (BMJ, Vol. 316, 1998).

Whitney et al tech of methods of preventing or reduction the risk of a first occurrence of a cardiovascular event using an HMG-CoA reductase inhibitor alone or in combination with another lipid altering agent (abstract). Examples of HMG-CoA inhibitors include atorvastatin (column 1, last paragraph). Atorvastatin in taught to sufficient treatment for myocardial infarction. Subjects to be treated with the instant methods are those having an average to mildly elevated serum total cholesterol level with is intended herein to be a level less than or equal to about 260 mg/dL (column 4, last paragraph). Furthermore, an average to mildly elevated low-density lipoprotein cholesterol level is 130 mg/dL to 190 mg/dL (column 5, first paragraph). Whitney et al further teach that the risk reduction of a fatal or non-fatal myocardial infaction using atorvastatin is expected to be at least 17 percent and more particular 17 to 57 percent (see column 9, lines 21-25, also note claims 36 and 37).

Kahn et al teach that platelet dependent arterial thrombosis underlies myocardial infarctions (page 879, column 1). The researchers address the roles of PAR-1 and PAR-4 in activation of human platelets by thrombin. It was demonstrated that PAR-1 and PAR-4 are functionally expressed in human platelets and that these receptors account for most if not all thrombin signaling in these cells (page 885, column 1). Because of the role of thrombin and platelet activation in myocardial infarction and other pathological processes, identifying and blocking the receptors by which thrombin activates platelets has been an important goal (page 886, column 2).

Gershlick et al teach that aspirin seems to be as beneficial as thrombolytic drugs and further that lifelong treatment with aspirin after myocardial infarction seems to be generally accepted (page 280, column 1). Further, it is known that aspirin affects the arachidonic acid pathway which activates platelet formation (page 283, column 1).

One of ordinary skill in the art would have been motivated to select patients with elevated PAR-1 and PAR-4 levels because it is well known that the activate PAR-1 and PAR-2 activate thrombin which activates platelets which in turn is the underlying cause of myocardial infarctions and also select an individual with elevated cholesterol and then administer an amount of a aspririn and a statin because each was known to treat myocardial infarctions for the screened populations. Further, one would be motivated to treat myocardial infarction with atorvastatin and aspirin in patients having elevated PAR and cholesterol both which are known for the effective treatment of myocardial infarctions. One would have been motivated to treat myocardial infarctions in patients with elevated PAR and cholesterol with atorvastatin and aspirin since they are both known to be therapeutically effective for treatment of the vascular disorder. Given that atorvastatin and aspirin are known to treat myocardial infarction one would expect that platelets would be inactivated and so would thrombin and therefore reducing the level of the receptors the elevated levels of PAR-1 and PAR-4 which activates thrombin, per Khan et al. Therefore, one would be motivated to select an individual with high PAR-1 and PAR-4 levels since high levels indicate high levels of thrombin which underlies myocardial infarction.

With respect to claim 1, the amount of a specific ingredient in a composition is clearly a result effective parameter that person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredients amount would have been obvious at the time of Applicant's invention.

Response to Applicant's Remarks

Applicant alleges that the claimed invention provides new methods of selecting individuals for statin administration to treat a vascular disorder, regardless of cholesterol levels. Further, Applicant

allege that there is no evidence in the cited references that teach and/or suggest the effect of statins on PAR-1 and/or PAR-4. This is not found persuasive. The open language of the claims necessarily includes the use of other steps and therefore the use of PAR-1 and/or PAR-4 levels to administer the instant agent in the dependent claims in combination with the cholesterol levels is obvious.

Conclusion

No claim is found to be allowable.

All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP
/Patricia A. Duffy/
Primary Examiner, Art Unit 1645